



**MTN-038**

# **Overview of Data Collection and Management**

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# Outline

- What we will cover
  - Rave/PTID basics
  - Randomization
  - Form population dynamics
  - MTN038-specific forms
  - Where to find more information

# Outline

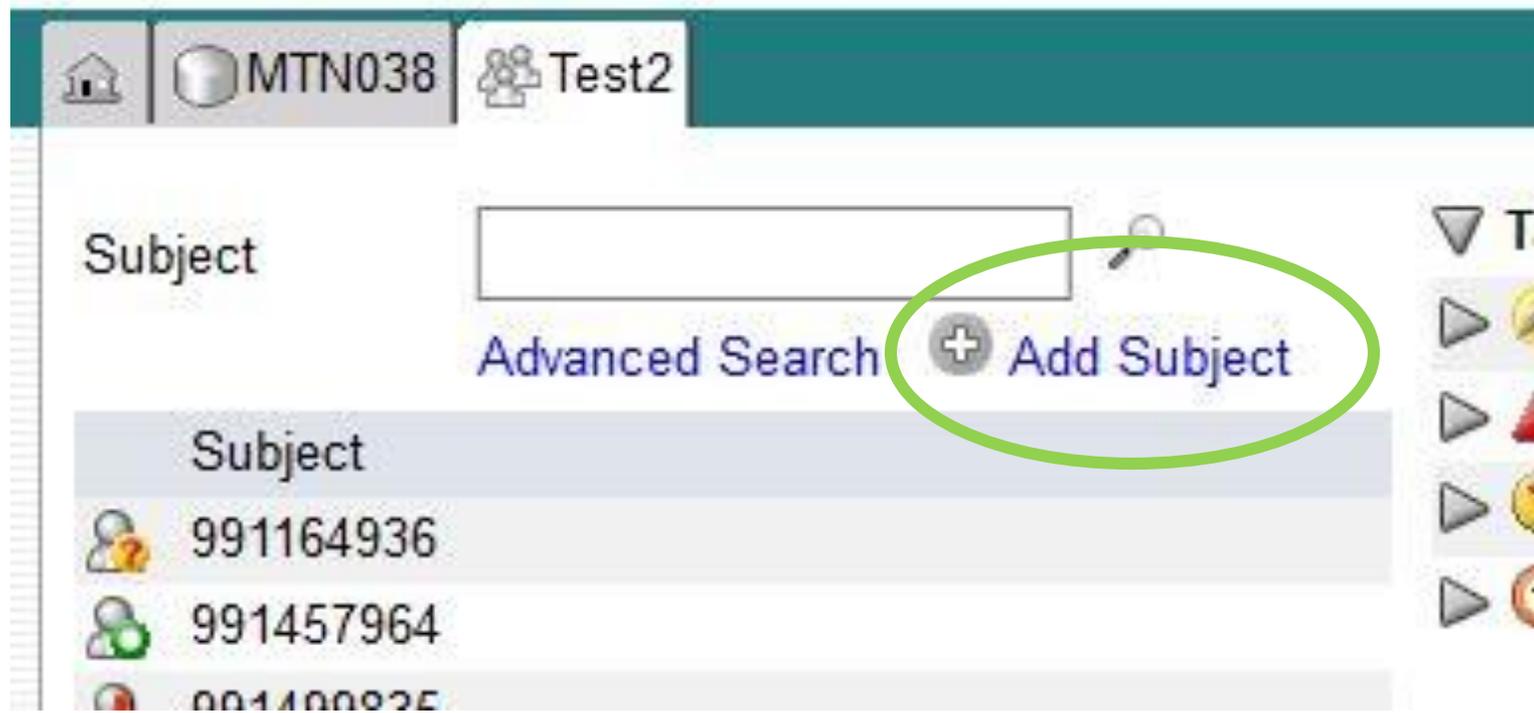
- What we will not cover
  - CASI
  - Rave manual
  - Query management
  - CCGs
  - Atlas
  - SSPs

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# Rave/PTID Basics

- “Add Subject” generates a PTID



# Rave/PTID Basics

- PTID structure

CRS Name	DAIDS ID	Rave ID
Birmingham	31788	821
Pittsburgh	1001	702
Bridge (SF)	30305	764

- Unique 9 digit identifier

XXX-YYYYYZ

Rave ID

Ppt ID + check digit

# Rave/PTID Basics

- The PTID-Name Linkage Log must be completed in real time. It is considered a source document for assigning PTIDs to participants.

	Participant ID	Name	Date ddMMMyy	Initials
1				
2				
3				
4				
5				
6				
7				

# Rave/PTID Basics

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- Direct data entry is strongly recommended. Site Data Management SOP should address data that will not be direct-entered.

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# Randomization

- Approx. 48 participants will be randomized in a 2:1 ratio to either 1.4 g TFV IVR or to a placebo IVR.
- The timing of biopsies will also be randomly assigned.
  - Both of these randomizations take place within the database.
- In addition, approx. 24 participants will be randomly selected for In-Depth Interviews (IDIs).
- The randomization schemes will be generated and maintained by the MTN SDMC and specified in the MTN-038 SSP manual.

# Randomization

- Participants will be randomized to In-Depth Interviews (IDIs) outside of Medidata Balance.
  - MTN SDMC will provide separate IDI randomization lists to each site.
  - After treatment group and biopsy schedule randomization in Balance, use the Randomization ID to find the IDI group on the IDI randomization list.

Randomization ID	Consider for IDI
201	Yes
202	Yes
203	No
204	No
205	No
206	Yes
207	Yes
208	Yes
209	No
210	Yes
211	Yes
212	Yes
213	No
214	No
215	No
216	No
217	Yes
218	Yes
219	Yes
220	Yes
221	No
222	Yes
223	Yes
224	Yes

*Example from MTN036*

# Randomization

- Document IDI Randomization on Enrollment CRF
  - Randomization ID can be found on the Randomization CRF in the Enrollment visit

Is the participant ready to be randomized?	Yes
Randomization Date and Time	11 SEP 2017 08:40:03
Randomization date	11 SEP 2017
Randomization ID	123456

- Document IDI in Enrollment CRF in Enrollment Visit

Page: Enrollment - V2 - Enrollment

Did the participant consent to long-term specimen storage and future testing?	<input type="radio"/> Yes <input type="radio"/> No
Treatment arm	<input type="radio"/> TFV Ring <input type="radio"/> Placebo Ring
Was the participant randomized to participate in IDI (In Depth Interview)?	<input type="radio"/> Yes <input type="radio"/> No
Was the participant invited to participate in IDIs?	<input type="radio"/> Yes <input type="radio"/> No
Will this participant participate in IDIs?	<input type="radio"/> Yes <input type="radio"/> No

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# Form Population Dynamics

- When you assign a PTID, all forms for Screening and Enrollment are automatically generated within a participant's visit folder, including Ongoing Logs

The screenshot displays a user interface for a clinical trial data management system. The top navigation bar includes the study identifier 'MTN038', the test name 'Test2', and a participant ID '991457964'. On the left, a sidebar shows a folder structure for the participant, with 'V1 - Screening' circled in purple. An arrow points from this folder to a detailed view of the 'V1 - Screening' form. This form is also circled in purple and lists various data collection points: Screening Date of Visit, Demographics, Hematology, Inclusion/Exclusion Criteria, Pregnancy Test Results, Medical History Y/N, Physical Exam, Vital Signs, Chemistry Panel - LFT, RFT, Other, Pelvic Exam, HIV Test Results, and STI Test Results. To the right of the form, a summary panel displays the subject ID '991457964', the page title 'Page: Screening Date of Vis', and the specific data point 'Screening visit date'. At the bottom of this panel, there are links for 'Printable Version', 'View PDF', and 'CRF Version 1116 - Page Generate'.

# Form Population Dynamics

- In order to populate the remaining visit folders for each participant:
  - 1) In the V1 - Screening folder, on the Inclusion/Exclusion Criteria form, click “Yes”, in response to “Did the participant meet all eligibility criteria?”

The screenshot displays a software interface for data entry. At the top, a teal header bar contains navigation icons and text: a home icon, 'MTN038', a group icon, 'Test2', a person icon, '991457964', a folder icon, 'V1 - Screening', and a document icon, 'Inclusion/Exclusion Criteria'. Below this, a sidebar on the left lists folders: 'V1 - Screening', 'Screening Date of Visit', 'Demographics', 'Hematology', 'Inclusion/Exclusion Criteria' (highlighted with a green circle), 'Pregnancy Test Results', and 'Medical History Y/N'. The main content area shows the form for 'Subject: 991457964' and 'Page: Inclusion/Exclusion Criteria - V1 - Screening'. A question is displayed: 'Did the participant meet all eligibility criteria?' with radio buttons for 'Yes' (selected) and 'No'. This question and its options are circled in green. Below the question is a field for 'Informed Consent Date' with a date picker and a dropdown menu.

# Form Population Dynamics

- In order to populate the remaining visit folders for each participant:
  - 2) ... and in the Enrollment folder, on the Randomization form, click “yes” on “Is the participant ready to be randomized?” Click “save”, and all the remaining visit folders will populate.

The screenshot displays a software interface for data entry. At the top, a teal header bar contains navigation icons and labels: a home icon, 'MTN038', 'Test2', a user icon with '99117358', a folder icon with 'V2 - Enrollment' (circled in green), and a document icon with 'Randomization'. Below the header, a left sidebar lists folders: 'V2 - Enrollment', 'Randomization' (circled in green), 'Enrollment', 'Pregnancy Test Results', 'Physical Exam', and 'Vital Signs'. The main content area shows the 'Randomization' form for 'Subject: 991173581'. The 'Page: Randomization - V2 - Enrollment' is indicated. A question, 'Is the participant ready to be randomized?' (circled in green), is followed by radio buttons for 'Yes' (selected) and 'No'. Below this is a field for 'Randomization Date and Time' with a help icon. The interface includes standard document icons for saving and printing.

# Form Population Dynamics

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- Regardless of whether or not a participant ultimately enrolls, please complete the Inclusion Exclusion Criteria and Demographics forms in the Screening folder for everyone who signs a consent form.

# Form Population Dynamics

- For every follow-up visit (V3-10), the “Follow-Up YN” form needs to be completed in order to populate the remainder of the forms for that visit.
- It is now standard for YN CRFs to populate their respective CRFs
  - this is a change! – used to have summary forms, now you need to fill out the YN form first
- Once a particular YN CRF has been completed with “Yes”, the respective CRF will populate for subsequent visits

# Form Population Dynamics

- The Demographics CRF you complete at Screening uses calculated age and other data to populate the lab module in Medidata.
- In Chemistry and Hematology CRFs, select lab FIRST:

Select your local lab first so that laboratory reference ranges can auto populate for each analyte being entered on the form.

MTN038 Test2 991457964 V1 - Screening Hematology

Subject: 991457964  
Page: Hematology - V1 - Screening

Lab ...

**HEMOGRAM**

Was a hematology sample collected?  Yes  No

Hematology collection date

# Form Population Dynamics

- Screening Forms
  - No AEs expected at Screening or Enrollment

The screenshot shows a medical form interface. At the top, there is a header bar with patient information: MTN038, Test2, 991457964, V1 - Screening, and Pelvic Exam. On the left, a navigation menu lists various form sections, with 'Pelvic Exam' highlighted. The main content area contains a section titled 'Complete or update Medical History Log or Adverse Event Log, as applicable.' Below this is a question: 'Were any new pelvic finding AEs reported at this visit?' with radio buttons for 'Yes' and 'No'. Below the question is a table with three rows for 'Adverse event #1', 'Adverse event #2', and 'Adverse event #3'. Each row has a text input field and a set of control icons (a circle, a pencil, and a square with an 'X').

Adverse event #	Description	Control
Adverse event #1		<input type="radio"/> <input type="radio"/> <input type="checkbox"/>
Adverse event #2		<input type="radio"/> <input type="radio"/> <input type="checkbox"/>
Adverse event #3		<input type="radio"/> <input type="radio"/> <input type="checkbox"/>

# Form Population Dynamics

- To Add Pregnancy & Interim visits
  - Find the “Add Event” dropdown menu
  - Menu located at the bottom of the ppt “home” page

The screenshot displays a user interface for a clinical trial. At the top, there is a header bar with icons for home, a participant ID 'MTN038', a test name 'Test2', and a user ID '991559168'. Below the header, a sidebar on the left lists various visit events for the participant, including 'V1 - Screening', 'V2 - Enrollment', 'V3 - Day 1 (1)', 'V4 - Day 7 (1)', 'V5 - Day 14 (1)', 'V6 - Day 28 (1)', 'V7 - Day 42 (1)', 'V8 - Day 56 (1)', 'V9 - Day 91 (1)', 'V10 - Day 92 (1)', 'Discontinuation (1)', 'Pharmacy (1)', and 'Ongoing Logs'. The main area shows a 'Participant Identifier' section with a table of visits. The table has columns for 'Visit', 'Date', and 'Ta'. The rows show 'V2 - Enrollment', 'V9 - Day 91 (1)', and 'V10 - Day 92 (1)'. At the bottom of the interface, there is an 'Add Event' dropdown menu and an 'Add' button, both of which are circled in purple.

Visit	Date	Ta
V2 - Enrollment		
V9 - Day 91 (1)		
V10 - Day 92 (1)		

Add Event  ...

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# MTN-038-specific forms

- PK Endpoints (Primary)
  - TFV concentrations in plasma
  - TFV concentrations in CVF
  - TFV concentrations in rectal fluid
  - TFV and TFV-DP concentrations in cervical tissue
  - Particular attention to timed specimen CRFs
    - Timed cervical specimen storage at enrollment (v2.0) and v9.0
    - Timed specimen storage at PUEV/v9 when ring is removed
    - Timed versions will supplant the “normal” forms

# MTN-038-specific forms

- Safety Endpoints (Primary)
  - “The proportion of participants with Grade 2 or higher genitourinary adverse event”
  - “The proportion of participants with Grade 3 or higher adverse event”

# MTN-038-specific forms

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- Secondary Endpoints
  - Frequency of study IVR removal/expulsions
  - IVR use initiation and persistence
  - Degree to which study participants liked or disliked using the IVR

# MTN-038-specific forms

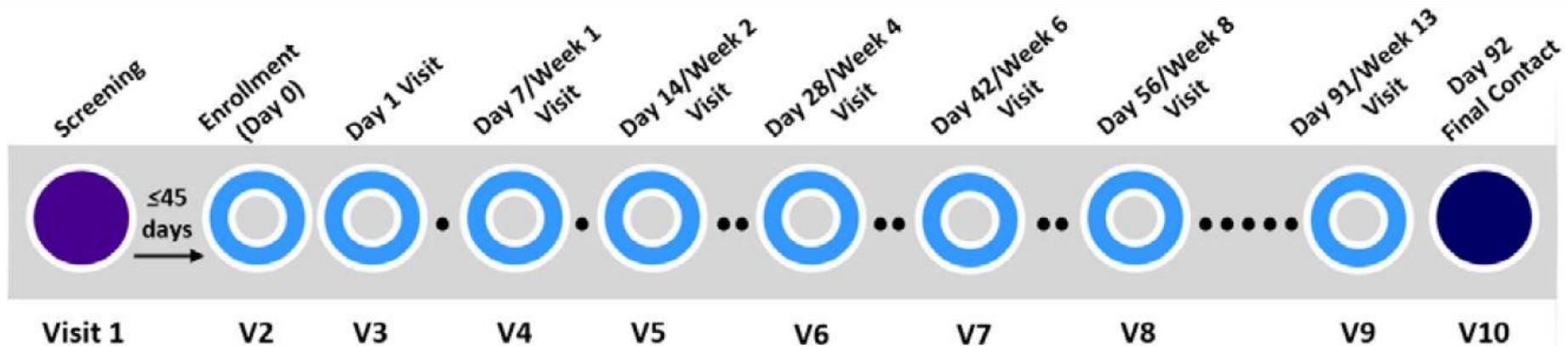
- Adverse Event (AE) Data
  - Report only one diagnosis, symptom or sign per page
    - Record unifying diagnosis whenever possible
  - Avoid using abbreviations
  - Review for correct spelling
    - Variations in spelling can lead to differences in AE coding, so similar AEs will appear differently in AE safety reports
  - Do not report surgeries as AEs (these are treatments)

# MTN-038-specific forms

- Adverse Event (AE) Data
  - Report ASAP, no later than 3 days following awareness
  - severity grading per usual
  - relationship to study product per usual
  - Action taken w/ study product per usual
  - SAE or EAE reporting per usual

# MTN-038-specific forms

- Visit Windows



- All enrollment procedures must occur on the same day.
- The participant's menstrual cycle must be considered when scheduling Visit 2- Enrollment (Day 0). Ideally, no bleeding should occur within the first 7 days of product use, e.g., Study Visits 2-4 (Days 0, 1, and 7).
- IVR provided at Visit 2, and collected at Visit 9.
- Participants will be randomized to provide cervical tissue samples at either Visits 5 and 8 (Days 14 and 56) or at Visits 6 and 9 (Days 28 and 91).

# MTN-038-specific forms

- Visit Windows

MTN-038 Visit Windows					
All windows are in days.					
Visit	Visit Code	Target Day	Window Opens	Window Closes	Visit Window Length
Screening	1.0	NA	≤ 45 days prior to Enrollment		NA
Visit 2 - Enrollment (Day 0)	2.0	0	NA	45 days after Screening Visit	45 days
Visit 3 - Day 1	3.0	1	1	1	1 day (Target only)
Visit 4 Day 7/Week 1	4.0	7	6	8	3 days (Target +/- 1)
Visit 5 Day 14/Week 2	5.0	14	12	16	5 days (Target +/- 2)
Visit 6 Day 28/Week 4	6.0	28	25	31	7 days (Target +/- 3)
Visit 7 Day 42/Week 6	7.0	42	39	45	7 days (Target +/- 3)
Visit 8 Day 56/Week 8	8.0	56	53	59	7 days (Target +/- 3)
Visit 9 Day 91/Week 13	9.0	91	89	93	5 days (Target +/- 2)
Visit 10 Day 92/Final Contact	10.0	92	24 - 72 hours after PUEV (Visit 9)		3 days (Target + 2)

# MTN-038-specific forms

- "Local Labs" CRFs changed to CHEM and HEME

The screenshot displays a web-based clinical trial form interface. At the top, a navigation bar includes a home icon, the study identifier 'MTN038', a test icon labeled 'Test2', a subject ID '991457964', a folder icon for 'V1 - Screening', and a document icon for 'Screening Date of Visit'. Below this, the main content area shows 'Subject: 991457964' and 'Page: Screening Date of Visit - V1 - Screening'. A form field for 'Screening visit date' is visible with a date picker. Below the form field are links for 'Printable Version', 'View PDF', and 'Icon Key', along with a 'CRF Version 1116 - Page Generated: 31 Aug 2018 12:28:19 Pacific Daylight Time' timestamp and a 'Save' button. On the left, a sidebar menu lists various form sections: 'V1 - Screening', 'Screening Date of Visit', 'Demographics', 'Hematology', 'Inclusion/Exclusion Cr', 'Pregnancy Test Result', 'Medical History Y/N', 'Physical Exam', 'Vital Signs', 'Chemistry Panel - LFT, RFT, Other', 'Pelvic Exam', 'HIV Test Results', and 'STI Test Results'. Two purple arrows point to the 'Hematology' and 'Chemistry Panel - LFT, RFT, Other' items, which are also circled in purple.

# MTN-038-specific forms

## Split Visits

- A visit is a split visit when the required visit procedures are split (done) over 2 or more days
- The days must *all* fall within allowable visit window; any required procedures not done within allowable window are missed
- For split visits, only 1 Follow-up Visit Summary eCRF is completed, and the Visit Date on this CRF is the date of the first part of the split visit
  - All CRFs completed for the split visit within the applicable study visit folder (e.g., CRFs completed for a split Visit 6 across Days 27 and 28 would all have visit code 6.0)

# MTN-038-specific forms

## Interim Visits

- Visits that take place between scheduled visits
  - Additional study procedures and/or data collection conducted outside of what is specified in protocol for required study visit (Example: Report of new AE, issue with study product, etc.)
  - Required study visit procedures conducted outside visit window, either to make up certain procedures from missed visit or conduct Visit 9 Early Termination Visit procedures due to early product discontinuation
- All interim contacts (e.g., phone calls and/or clinic visits) will be properly documented in study files and on applicable CRFs

# MTN-038-specific forms

## Missed Visits

- A visit is missed when:
  - No part of a visit is conducted within the allowable visit window, OR,
  - A visit does not have a window, and the participant cannot come in on target day.
    - For 038, the visit that meets this definition is Visit 3.
- Missed visits are not made up. Rather, sites should make every attempt to retain participants at future visits.

# MTN-038-specific forms

If a participant does miss a visit:

- Document in the database using the Missed Visit CRF
- The Missed Visit form will let SCHARP know not to expect any other forms for that participant at that study visit (with the exception of the Follow-up Yes/No CRF).
- The Missed Visit CRF is completed in lieu of a Protocol Deviations Log CRF

The screenshot displays a web-based data entry interface. At the top, a teal header bar contains navigation icons and text: 'MTN033', 'Test3', '991930497', 'V3 - Dosing visit (1)', and 'Follow-up Visit Y/N'. Below the header, a sidebar on the left lists three CRF forms: 'V3 - Dosing visit (1)', 'Follow-up Visit Y/N', and 'Missed Visit', with the 'Missed Visit' form highlighted by a blue box. The main content area shows the following text: 'Subject: 991930497', 'Page: Follow-up Visit Y/N - V3 - Dosing visit (1)', and the question 'Did the participant complete this visit?'. Below this question are links for 'Printable Version', 'View PDF', and 'Icon Key', followed by the text 'CRF Version 669 - Page Generated: 26 Feb 2018 11:39:14 Pacific Standard Time'. On the right side, there are icons for 'No', 'Save', and 'Cancel', with the 'Save' button highlighted by a blue box.

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# Where to find more information

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- CRF Completion Guidelines (CCGs) to aid in form completion will be available on the MTN-038 ATLAS webpage
- Help text available on select items within Rave to provide key guidance on form completion
- Site Specific Procedures (SSPs) will also provide data-related guidance.

# Where to find more information

- Last Day to Enroll calendar tool
  - Will be available on study website
  - <https://mtnstopshiv.org/research/studies/mtn-038>
  - Example from MTN 036

Network Research People Meetings Resources

Research > Studies > MTN-036/IPM 047

## MTN-036/IPM 047

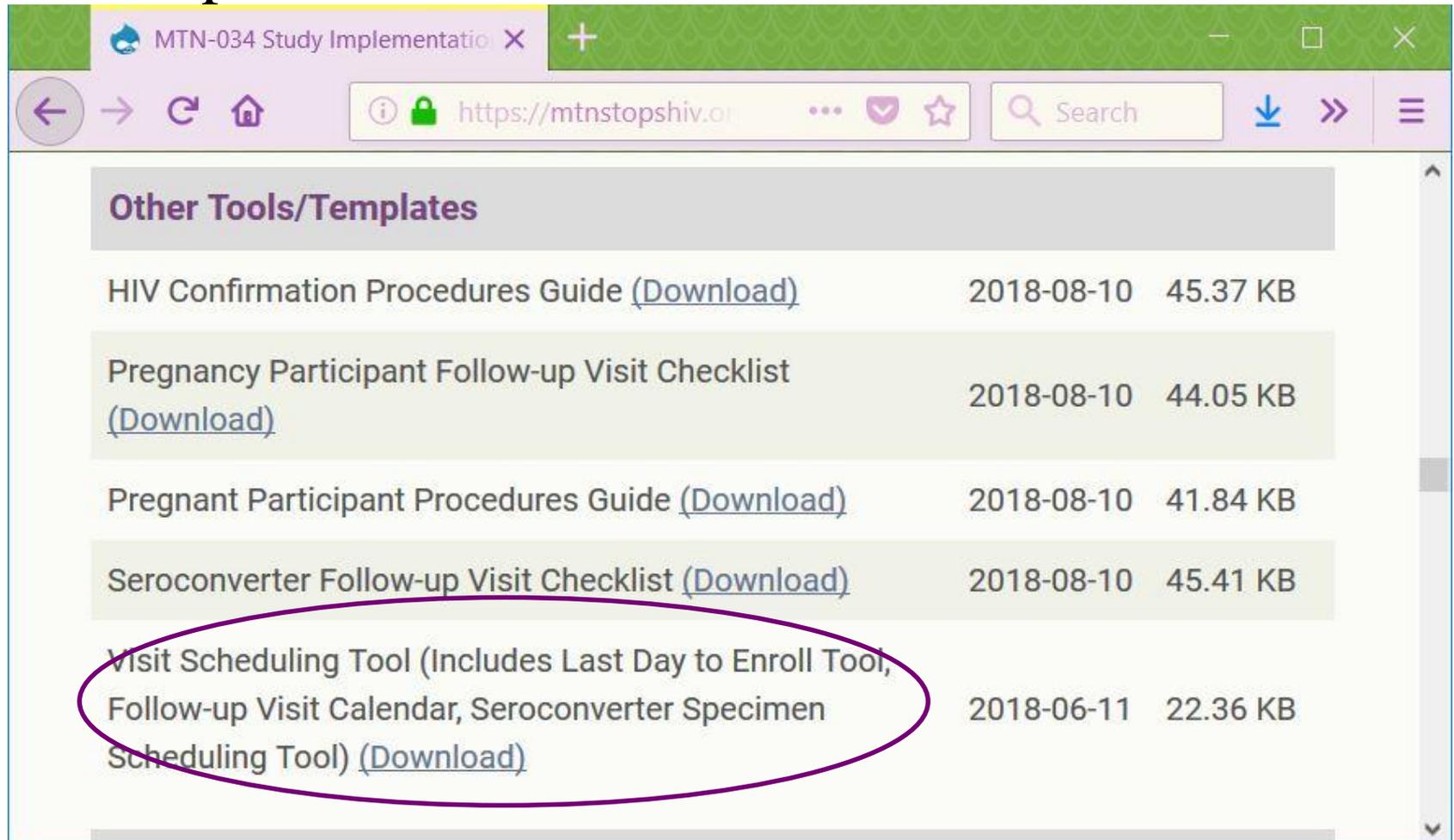
MTN-036/IPM 047 is a Phase 1, randomized, three-arm, open label trial. The study will assess the safety and pharmacokinetics (PK) of three silicone elastomer intravaginal rings (VRs) containing either 25 mg or 200 mg of the active ingredient dapivirine (DPV) formulated using either polymer 4320 or 4870. Approximately 36 healthy, HIV-uninfected, non-pregnant women between 18-45 years of age will be followed for approximately 97 days. Participants will insert one VR to be used continuously for 90 days (200 mg VRs) or replaced monthly for 3 months (25 mg VR). Accrual is expected to take 6-9 months. MTN-036/IPM 047 will collect local and systemic pharmacokinetic data as well as safety information on the vaginal rings. MTN-036/IPM 047 will also investigate the acceptability of and adherence to the VRs and explore changes in vaginal microflora and biomarkers over 90 days of product use.

### Study Links

- Clarification Memos
- Internal Documents
- Letters of Amendment
- Operational Guidance
- Protocols
- SSP Manual
- Study Implementation Materials**
- Training

# Where to find more information

- Example from MTN034



The screenshot shows a web browser window with the address bar displaying 'https://mtnstopshiv.org'. The page content is titled 'Other Tools/Templates' and lists several documents with their dates and sizes. The 'Visit Scheduling Tool' entry is circled in purple.

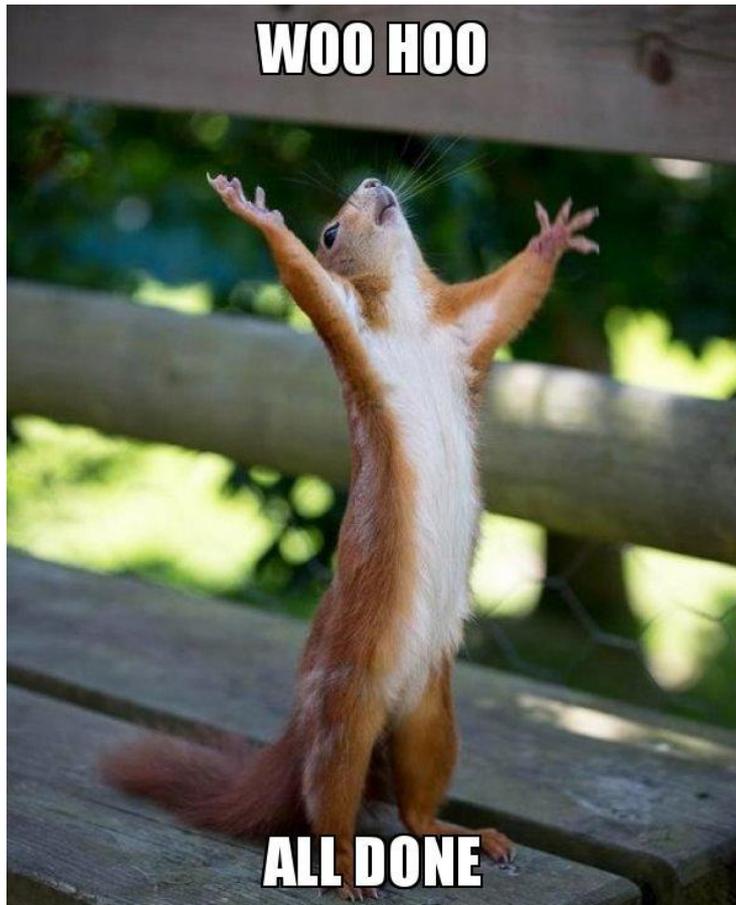
Tool/Template Name	Date	Size
HIV Confirmation Procedures Guide ( <a href="#">Download</a> )	2018-08-10	45.37 KB
Pregnancy Participant Follow-up Visit Checklist ( <a href="#">Download</a> )	2018-08-10	44.05 KB
Pregnant Participant Procedures Guide ( <a href="#">Download</a> )	2018-08-10	41.84 KB
Seroconverter Follow-up Visit Checklist ( <a href="#">Download</a> )	2018-08-10	45.41 KB
Visit Scheduling Tool (Includes Last Day to Enroll Tool, Follow-up Visit Calendar, Seroconverter Specimen Scheduling Tool) ( <a href="#">Download</a> )	2018-06-11	22.36 KB

	A	B	C	D	
1	<b>MTN-034 - Calculation of Last Possible Day to Enroll</b>				
2					
3					
4	<b>Screening Visit Date:</b> <i>Date Screening Consent marked or signed</i>		<b>Monday, January 8, 2018</b>	<b>Instructions:</b> 1. Enter Screening order to generate the participant c REACH. 2. Enter the date participant initi method of contra generate the first that the particpa enrolled based c criteria #9. Do n participant prior	
5			<i>Enter as dd-mmm-yy</i>		
6					
7	<b>Date participant initiates effective method of contraception:</b>		<b>Wednesday, January 10, 2018</b>		
8			<i>Enter as dd-mmm-yy</i>		
9					
10	<b>First possible Enrolment date based on initiation of effective method of contraception:</b>		<b>Sunday, March 11, 2018</b>		<i>Per inclusion criteria must use an effective contraception for a prior to En</i>
11			<i>Shown as dd-mmm-yy</i>		
12					
	<b>Last Day to Enroll:</b>		<b>Monday, March 19, 2018</b>		

# Where to find more information

- For non-protocol specific overviews:
  - <https://mtnstopshiv.org/research/studies/mtn-020/study-implementation-materials/clinical-research-training>
- For Medidata RAVE:
  - [www.imedidata.com](http://www.imedidata.com)
- For help with ATLAS:
  - <https://atlas.scharp.org/>

# Questions?



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